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6 QUALITY CONTROL

Quality control (QC) and quality assurance (QA) procedures were planned for and implemented throughout the 1997 Air Force Health Study (AFHS), from project initiation to final product delivery and acceptance by the Air Force. QC is defined as the procedures put in place to ensure the quality of the data collected. QA refers to the management of those procedures. This chapter provides an overview of the specific QC and QA measures developed and used by the project team, specifically in the areas of questionnaire and physical examination QC, laboratory QC measures, data management QC, statistical QC, and administrative QA. The Air Force, Science Applications International Corporation (SAIC), the National Opinion Research Center (NORC), and Scripps Clinic all participated in the formulation and implementation of the QC and QA procedures described in this chapter.

6.1 QUESTIONNAIRE QC

6.1.1 Design

For the baseline and subsequent follow-up examinations, the baseline and interval questionnaires were administered in person. In the examinations prior to 1997, the questionnaires were administered in hard copy, which was then key-entered into the final SAS®[1] data set. For the 1997 follow-up, the interview responses were obtained electronically on laptop computers, using a computer-assisted personal interview (CAPI) system.

Effective CAPI design was the first step in QC of the data collection. By combining the two steps of data collection and data entry, the CAPI technique eliminated one possible source of recording error—key-entry of the data. Further, the logic checks, range checks, and intervariable consistency checks programmed into the CAPI system placed constraints on what the interviewer could type or select for any particular question during the interview. These constraints limited keystroke errors and data problems arising from the interview itself. The structure of the CAPI system ensured that skip patterns were followed correctly and that no questions were left unanswered. In certain sections of the questionnaire, CAPI offered significant enhancements to the flow and accuracy of the questionnaire over a paper-and-pencil execution. These enhancements included automatic unit conversions and elimination of multiform cross-references. These benefits were most notable in the calculations of alcohol and tobacco use and in updating information for children born prior to the last interview.

Using a process of reviewing, commenting, and concurring, Air Force researchers and NORC designers incorporated new questions and questions derived from the AFHS self-administered forms into the 1997 questionnaire. The goal was to create a cohesive instrument with questions grouped logically by subject because a cohesive questionnaire would enhance the participant's focus on the subject being discussed and his understanding of the questions. In addition, the inclusion of the self-administered forms into the interval questionnaire decreased the participants' frustrations with the study process by eliminating question redundancy, providing a logical sequencing of questions, and decreasing the time spent by the participant.

[1] SAS and all other SAS Institute, Inc., product and service names are registered trademarks or trademarks of SAS Institute, Inc., in the USA and other countries.

An additional benefit of the CAPI questionnaire was the ability to print selected participant responses for the use of the debriefing physicians. These printouts were improved and refined during the physical examination period.

6.1.2 Data Collection

NORC recruited and trained eight interviewers and one field manager to administer the baseline and interval questionnaires. A minimum number of interviewers were selected to reduce variability between interviewing techniques. The interviewers were blind to the participants' exposure status, thus avoiding bias.

The Field Manager, who supervised the interviewing at the examination site, observed the work of each interviewer and presented formal evaluations of their performance each quarter to the Air Force. Interviewers were evaluated on their ability to control the interview and to probe incomplete answers in a neutral manner. They also were graded on their vocal quality, reading quality, and on their use of associated forms and documents. The interviewers were graded on a scale of 1 to 4. A rating of 1 indicated an unacceptable performance and 4 an above-average performance with no errors. All interviewers performed at an above-average level and none required retraining.

Interviewers were required to regularly report questions or problems experienced while executing the questionnaires. "CAPI Problem Forms" and "Policy Decision Forms" were distributed for interviewers to complete, and these forms were faxed daily to the Data Collection Task Leader at NORC headquarters in Chicago, Illinois. Items reported on the forms included the following: (1) mistakes made and not corrected during the interview, (2) conditions reported by the participant after the interview was over, (3) technical problems with the CAPI instrument, and (4) problems with the printout for the debriefing physician. The Data Collection Task Leader corrected problems when necessary and provided assistance to interviewers in handling confusing or unusual situations.

6.1.3 Processing and QA of Questionnaire Data

Completed questionnaire data were transmitted daily via modem from the La Jolla, California, site to the receiving computer system in Chicago. As interviews were completed on the laptop computers at the site office, the CAPI system selected the newly completed cases, encrypted the interview data, and transmitted the interview data to the NORC modem pool in Chicago. Once in Chicago, the interview data were unencrypted, archived on a devoted volume of the NORC UNIX computer, and copied to the NORC wide area network. Each CAPI interview consisted of one multiple-record ASCII file representing the participant's answers to questions. Using a standard utility, the ASCII files were converted from their vertical format to the horizontal format readable by SAS®. Programmers then read the horizontal files into SAS® and printed frequencies of all variables. Case data received in Chicago were reconciled regularly with the completion log at the interviewing site.

Some of the QC steps used in converting CAPI files to the SAS® data files include the following:

1. The case IDs of all completed interviews in the SAS® file were compared to the log of completed interviews kept at the site office. This ensured that all completed cases were received and that there were no duplicates.
2. The SAS® variables were compared to a hard-copy representation of the CAPI to ensure that all questions in the interview were present in the SAS® data file.

3. The response frequencies were compared to a hard-copy representation of the CAPI to ensure that no data were truncated.

One of the goals in the conversion process was to replicate, to the maximum extent possible, the variable names, formats, and structures used in the 1992 SAS® data set. To accommodate this goal, additional "post-processing" programs were created. The post-processing included renaming variables, assigning the appropriate variable labels and value labels, creating variables based on values of answers to more than one question (such as calculations of cigarette use), and merging variables collected outside of the interview into the data set.

Several steps were taken to ensure that the SAS® data file created from the post-processing programs contained the correct information:

- A list was created that mapped CAPI variables to SAS® variables. This allowed the NORC staff to ensure that variables were named properly and that all required variables were included in the SAS® data set.
- Format statements and frequencies were proofed against three representations of the questionnaire (the CAPI form, the 1997 hard copy representation, and the 1992 hard copy) to detect problems.
- Cross-tabulations and printouts of data items at the case level were generated to investigate complicated questions, such as whether a calculation was working correctly or why there was a missing value in a certain variable.
- Continuous reviews of the frequencies were performed until no more errors were detected.
- A cumulative data set of all interviews completed to date, accompanied by a footnote file explaining any anomalies or errors still to be resolved, was delivered quarterly and then monthly to the Air Force for review. All errors identified by the Air Force were corrected by NORC, the data set was corrected and delivered a final time, and the corrections were accepted.

Response frequencies for all data fields were reviewed regularly to ensure that data for all variables were captured, answers made logical sense, and the skips and checks programmed by CAPI were operating correctly. These QC checks revealed a small number of problems in the questionnaire, all of which were corrected without significant loss of data. These problems, along with the solutions applied, were documented in the footnotes included with the data file.

One of these problems was discovered during processing of the first questionnaires. During a variable-by-variable review of the interval questionnaire, NORC discovered that a short series of questions concerning mental and emotional illness had been omitted from the CAPI program. Three steps were taken to correct this situation:

1. A hard-copy version of the questions was immediately distributed to NORC's interviewers at Scripps Clinic so that the information would be obtained for the remaining participants in the current physical examination group. These data were manually entered into the questionnaire database.
2. A revised version of the interval questionnaire, containing the omitted questions, was installed on the interviewers' computers within 6 calendar days of the problem discovery.

3. NORC schedulers telephoned the participants who were not asked the omitted questions during their in-person interview to retrieve the information. These data were manually entered into the questionnaire database.

6.2 PHYSICAL EXAMINATION QC

The Scripps Clinic selection process for all personnel who were to interact directly with the participants ensured a high-quality physical examination. Each staff member was hand-selected for the AFHS on the basis of expertise, experience, and a commitment to remain with the study throughout the examination process. Further, the Air Force reviewed the credentials of all key staff members and approved their participation in the study.

A complete pre-examination test was held. Eleven volunteers completed the physical examinations, interviews, psychological tests, and laboratory analyses several weeks before the scheduled start of the study. All aspects of patient contact were reviewed: the initial inbriefing of the participants, the logistics of transportation and patient flow within the clinic, and the final outbriefing by the diagnostician.

During the actual examinations, refinements were made whenever operational problems were detected. Whether detected by the Scripps staff, the Air Force onsite monitor, or the participants, study problems were addressed during periodic clinical QA meetings of key Scripps staff. For instance, participant temperatures were not recorded for the first few physical examination groups. This error in protocol was addressed in one of these meetings. The Air Force reviewed the affected records, found no comments concerning elevated temperatures, and coded these records as normal.

During the physical examination, the identification of 27 chest x rays was found to be questionable because of incomplete or improper labeling. Although no data from the x rays were to be used in the analysis, the 27 participants whose x rays were in question were contacted and arrangements were made to reshoot their x rays. All but six x rays were retaken; two participants refused.

Following examination of each participant group, the Scripps staff reviewed all physical examination forms for omissions, incomplete examinations, and inconsistencies. When issues were found, the examiners or technicians were contacted to correct the data. Special effort was made to complete this review while the participants were at the examination site. In all cases in which data were corrected, the form was initialed by the doctor or technician making the correction. (This subject is discussed in more detail in the Medical Data QC section of this chapter.) An optical scanner read all mark-sense physical examination forms as an ongoing QA of form completion.

The Air Force onsite monitor and the Scripps Clinic administrative team monitored compliance with the physical examination process. The Scripps Clinic Chief of Medicine and the SAIC Project Manager conducted additional periodic inspections. All such clinical reviews were performed unobtrusively and with the full consent of the participant; suggestions or corrections to the examination procedure always were discussed privately with the attending physician. These inspections emphasized aspects of clinical techniques, sequence, and completeness of the clinical data with respect to the examination forms and the blindness of the examinations. Of particular note were the detailed daily log entries of the Air Force monitors. These entries ensured continuity of knowledge (the monitors rotated approximately every 2 weeks) by documenting daily activities and, when needed, recording events requiring follow-up by either the Air Force or SAIC.

Establishing a rapport with each study participant was a primary goal of all the organizations involved in the study. Although this may not be a traditional QA parameter in most research studies, it is paramount in the AFHS. Maintaining participants' satisfaction encourages them to continue in the study, thus avoiding the need for significant participant replacement, which can reduce future statistical power or introduce bias, or both. Therefore, every staff member emphasized courtesy, empathy, assistance, and personalized treatment of each participant.

Participants were asked to fill out an evaluation form after completion of their 1997 follow-up physical examinations. The participant evaluations provided insight into the participants' experiences, including strong points of the programs and areas in need of improvement. These forms were reviewed by all study management staff.

Based on the participants' evaluation forms, 72.8 percent evaluated their overall clinic experience as excellent, and 25.0 percent classified it as good. One participant felt that the experience was unsatisfactory, and 2.1 percent of the participants rated it as satisfactory. Figure 6-1 charts those evaluations of the participants' clinic experiences.

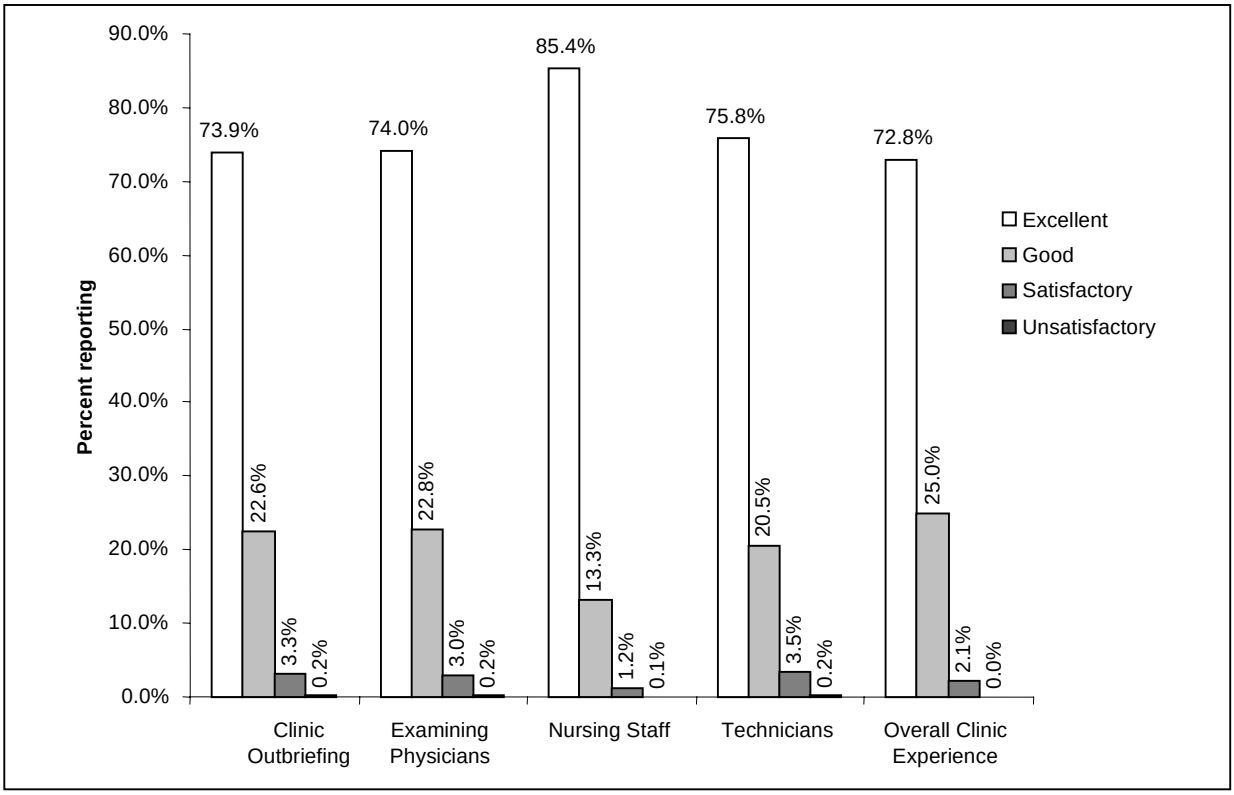

Figure 6-1. Participant Evaluations of the 1997 AFHS Clinic Experience

6.3 LABORATORY QC

Before the study began, specific QC laboratory procedures were designed, developed, and implemented to detect problems related to test and assay performance, validity of reagents, analysis of data, and reporting of results. All laboratory assays for the study were performed with state-of-the-art laboratory equipment and techniques. Laboratory facilities all had the equivalent of National Institutes of Health Biosafety Level 2 approval ratings and were certified by the College of American Pathology.

6.3.1 QC Procedures for the Clinical Laboratory

The following list outlines the tests performed and the methods and equipment used:

- Hematology assays were performed on Coulter STKS® equipment.
- Erythrocyte sedimentation rate determinations were performed using the large-tube Westergren method.
- Biochemical assays were performed using the Dade RxL® Automated Chemical Analyzer.
- Radioimmunoassays were performed with standard test kits.
- Electrophoresis and occult blood tests were performed manually.
- Hepatitis A, B, C, and D tests were performed using Abbott Commander® and Quantum® machines.
- Monospecific antibodies were used for immunoglobulin assays using the Beckman Array Protein System®.
- T & B lymphocytes were analyzed on BD FACSCAN equipment.
- Blood-cell counts were performed with standard microscopy.
- All urinalyses were performed using Bayer Atlas® equipment.
- All other assays were performed using industry-standard equipment and techniques.

All laboratory operations were controlled with the use of an integrated medical laboratory management information system that incorporated direct device-to-database interfaces for automated testing equipment. Laboratory technologists performed data entry for manual tests. An automated audit trail and a set of comments for technologist remarks were kept for each test so that any QC results could be retraced.

Procedural QC included using the same instrument and reagents from the same lot numbers whenever possible throughout the study. If single lots were unavailable, analyses were conducted to calibrate subsequent lots and establish target levels and associated standard deviations. Strict standards of calibration for all automated laboratory equipment were maintained at all times.

Trilevel or bilevel controls were used as the primary means for monitoring the quality of all tests. On every group of participant samples, one control (low, medium, or high) was run at the start, after every ninth sample, and at the end of each test run. Each trilevel control was used before repeating it in the run when more than 18 experimental samples were analyzed. In addition, split aliquots were created from every 10th participant sample and were analyzed separately to measure test reproducibility. In radioimmunoassays, all three control levels were run initially to validate the standard curve generated.

Scripps Clinic Medical Laboratory has defined quality requirements of accuracy above 99 percent and levels of precision above 97 percent. A variation of the Westgard Rules (1, 2) QC technique is routinely used in the Scripps Laboratory and was used for AFHS assays. In this variation, the 1_{2s} single rule and 4_{1s} multiple rule are used. The 1_{2s} rule indicates rejection of any run when the control value of any one of the three controls (low, mid, high) exceeds two standard deviations from the mean. The 4_{1s} rule indicates rejection of a run when four consecutive control measurements exceed one standard deviation on the same side. This approach ensures an effective system for reducing the probability of false rejection to the lowest acceptable level while maintaining error detection at more than 98 percent.

All QC data were analyzed and summarized in formal QC reports generated monthly. QC data were subjected to independent statistical analysis by the Air Force to produce and analyze time-dependent trends. For all equipment malfunctions or other exceptions, a formal QC exception report was prepared by the responsible individual and forwarded to the project management team. A summary of the coefficients of variation for each quantitative laboratory assay is presented in Appendix D. These coefficients of variation are given separately for each control level and lot.

As the examination portion of this study ended, an independent clinician analyzed laboratory outliers for logical validity. All out-of-range test results were examined and scored as "clinically explainable," "clinically possible," or "clinically unexplained." No clinical laboratory data were excluded from the report analyses because all potential out-of-range results were found to be clinically explainable or clinically possible.

6.4 MEDICAL DATA QC

6.4.1 Overview of QC Procedures

The QC procedures for the medical data consisted of multiple checks at all stages of the examination, data collection, and data processing cycle. A representation of the QC process is given in Figure 6-2. Although improvements were made throughout the physical examination period, QC procedures for data collection, conversion, and integration were developed before the clinical examinations began. All data collection instruments were tested at the pre-examination test conducted several weeks before the start of participant physical examinations. In addition, during the first 2 months of the clinical examinations, all data collection activities were routinely scrutinized to detect and correct procedural deficiencies. Other QC activities included the following:

- Automated QC techniques applied to laboratory data
- Clinical evaluations of all laboratory outliers
- Review of all physical examination findings by one of two diagnosticians
- Automated and manual data quality checking of hard copy against transcribed computer files.

Four interwoven layers of QC were instituted to ensure data integrity. These efforts focused on (1) data processing system design, (2) design and administration of all exams, (3) data completeness checks, and (4) data validation. In addition, Air Force investigators reviewed all physical examination forms and entries. Forms that were found to be questionable, inaccurate, or incorrect were returned to Scripps Clinic for adjudication.

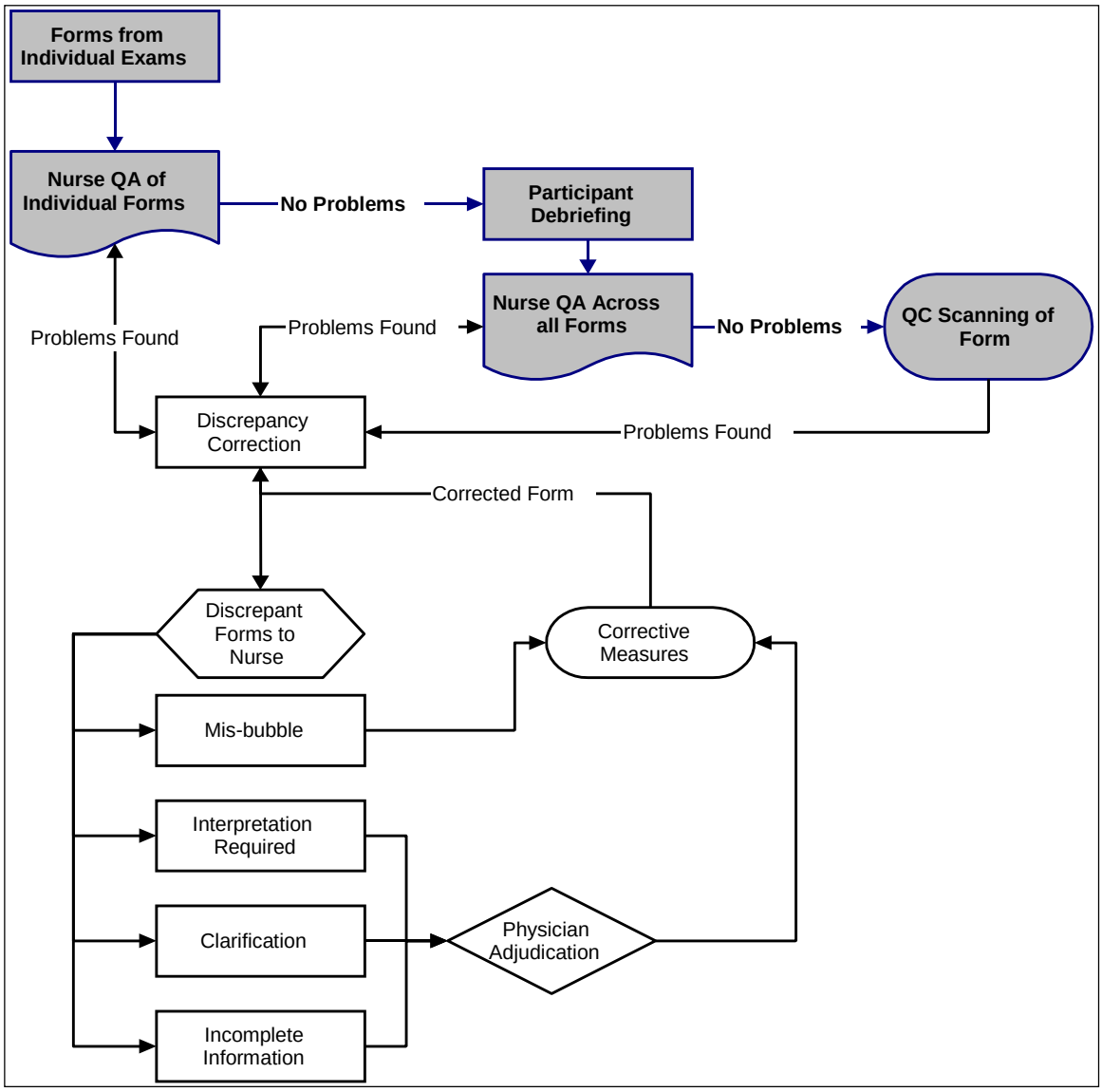

Figure 6-2. Physical Examination Form QC Process

6.4.2 Data Processing System Design

Standards were established for data element formats (character or numeric), data element naming conventions, data element text labels, numeric codes for qualitative responses and results, QC range checks for continuous data elements, and QC validity checks for categorical data. A data dictionary provided detailed information on each data element.

A systems integration approach was applied to the design and implementation of data collection procedures so that data emanating from study sources (physical examination, questionnaire, and laboratory) were consistent in file format and structure. This approach was necessary to ensure that all data could be integrated into a single database for analysis.

Data collection forms were carefully designed to ensure that all required data elements would be collected in accordance with the study protocol and in a standardized format. These instruments were designed to reflect the order in which the examination itself would be administered and to provide for the sequential coding of information.

Completed clinical examination forms were converted from hard copy to machine-readable images using optical mark reading equipment. Verification procedures were performed to ensure that a uniquely identified participant record existed within each data file and that the appropriate number of responses for each applicable field was provided. Data files were then translated into a SAS® data set, verified against original data sheets, and corrected as necessary. All corrections to the original data sets were saved in the processing program, which was delivered to the Air Force for verification.

Next, the SAS® data sets were subjected to validity checks. All potentially conflicting results, as well as any data values falling at the extremes of expected ranges, were manually reviewed. Extreme values were verified against the original data forms and either corrected or documented as valid results. Potentially conflicting results, either within one form or among forms, were returned to the examiners for review. These results were then documented as having been correctly recorded, corrected, or flagged for exclusion from analysis because of unresolvable examiner errors or omissions. This process was continued until all results were properly documented.

The validity checks were tested with the delivery of the first cumulative medical results data. At that time, it was discovered that some data were not properly cross-checked between collection forms. The discrepancies were adjudicated by the appropriate Scripps Clinic staff and corrected on the forms and in the database in accordance with the QC procedure. Additional QC steps were added to the procedures because of these discrepancies.

Once the edits were completed and the data verified, the "cleaned" files were transferred to the data analysis center for final inspection and integration into the study database. In this QC measure, descriptive analyses were run. The validation, correction, transmission, and analysis QC procedures were repeated as necessary to ensure that all extreme or suspicious values had been validated. As an additional measure of QC, cumulative result data sets were delivered quarterly during the physical examination phase for Air Force review. The data sets were finalized following the close of the physical examinations and before the start of statistical analysis. The process for cleaning and converting the collected data into final data sets is found in Figure 6-3.

6.4.3 Design and Administration of Physical and Psychological Examination Forms

The examination forms were designed to elicit all required data while minimizing recording time, enhancing comprehension, and automating data input. Customized mark-sense forms were developed and optical mark recognition technology (OMR) was used to eliminate the risk of transcription errors. The use of mark-sense forms allowed the creation of computerized data files directly from the raw data recorded on these forms.

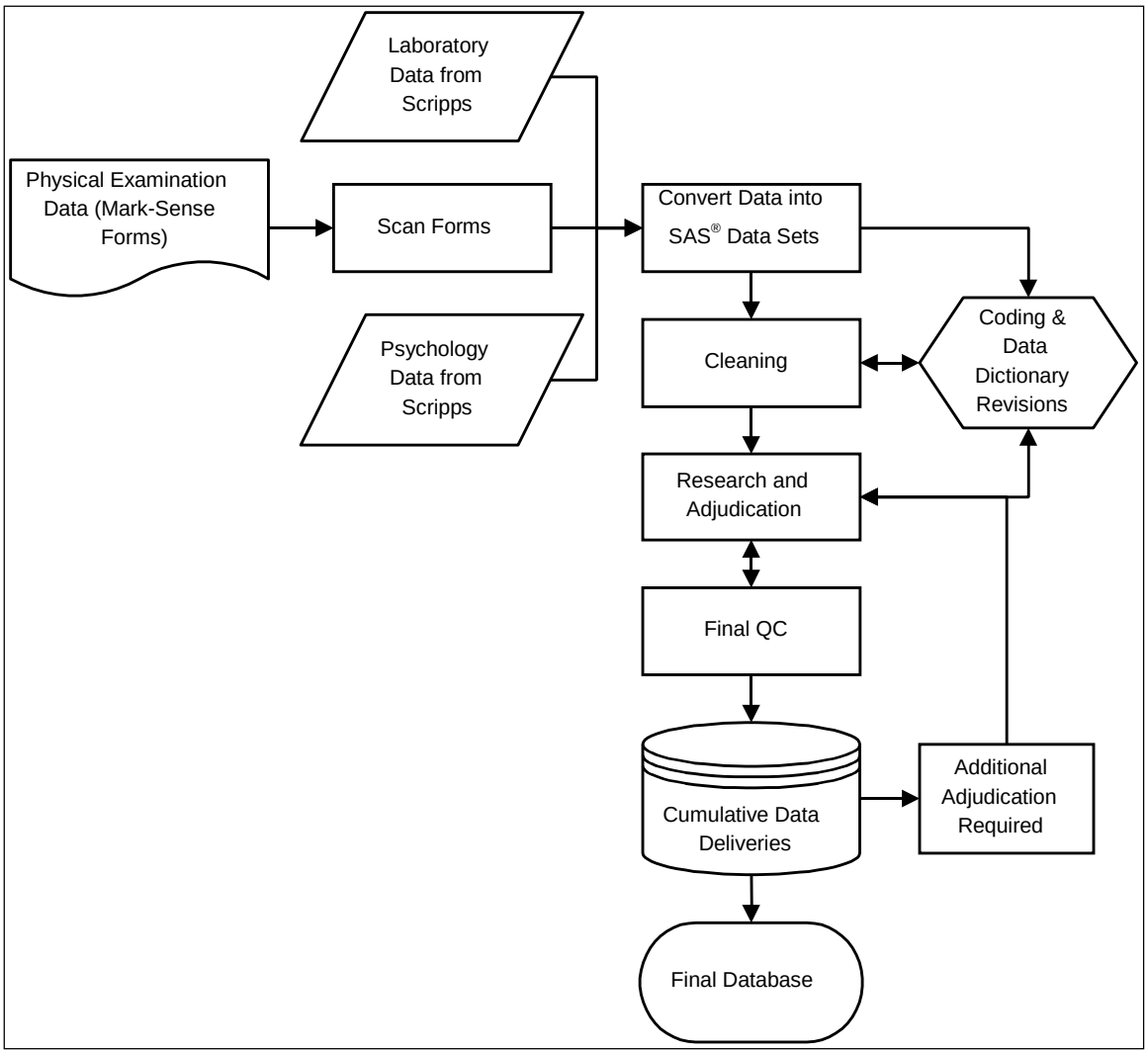

Figure 6-3. Conversion and Cleaning Process for Medical Data

QC procedures for all data collection instruments began with both manual and electronic reviews of each form as it was completed. A mark-sense reader was used at Scripps Clinic to scan for completeness and to conduct some broad-based logic checks. Any forms containing missing, incomplete, or contradictory examination results were returned to the examining physician for completion before the participants left the site. Any questionable results or "hard-to-diagnose" conditions (such as heart sounds or peripheral pulses) were verified by the diagnostician at the outbriefing. In addition, any differences in interpretation among examiners were identified, and adjustments in recording protocols and programmed data extraction were made as necessary. All examination forms were signed by the examining physician, and the examiner identification number was coded in the database.

6.4.4 Data Completeness Checks

Customized programming of the OMR allowed for the identification of those forms (and their corresponding data records) with missing responses, as well as those with multiple responses to questions that required a single response. The OMR scanner was programmed to reject forms that failed

completeness and multiple response checks and to generate a control code for each rejected form. The control code identified the location of all verification checks failed for a given form.

When a data collection form was rejected, the reason for the rejection was determined. The exact data element was then corrected by comparing the rejected form to the values recorded in the data record created by the scanner. Some of the rejected forms did not contain actual data errors, but rather anomalies created in using mark-sense forms for data collection. For example, the scanner incorrectly counted incompletely erased responses and missed responses marked with too little carbon or graphite. In addition, examiners tended to mark responses clearly for abnormal findings and to mark responses lightly or to bypass responses for expected or desired findings. Failure of the form to provide the correct number of expected responses always resulted in rejection. These errors were resolved, as were the anticipated, more traditional errors.

Out-of-range results and data omissions were monitored to detect trends, possible bias situations, and other data-quality problems. This information was reviewed and relayed to examiners and internal auditors to assist in preventing or correcting chronic, but avoidable, problems. Refresher training was provided to examining physicians to avoid data omissions. Physicians were consulted to correct clinical data, and laboratory out-of-range results were reviewed for logical validity by an independent clinician.

6.4.5 Data Validation

Data files were examined in a series of verification and validation procedures developed to check the results within each participant's record for logical consistency and abnormal findings. Any records noted to have ambiguous findings, incongruent observations, extreme results, errors, or omissions were listed and submitted for review to a physician. Data items that could not be definitively validated or recovered through consultation with the original examiner were assigned codes noting missing or invalid data values. Some reasons for unavailable data included the following:

- Participant refusal
- Unscorable psychological tests
- Test not ordered (e.g., immunology tests, which were only ordered for a subset of the participants)
- Exemption from testing (e.g., exemption from postprandial glucose testing because of diabetes).

These unrecoverable data were excluded from subsequent analysis. The number of values not available for analyses is presented in each clinical chapter by variable.

In the validation process, transcription errors were found between the two dermatology data collection forms. Although these data were not to be analyzed for this report, all forms were manually checked and corrections were made by the dermatologist.

In validating the genitourinary data, SAIC found 14 participant records with inconsistent information. In all cases either the right testis, or both the left and right testes, were not indicated as normal or abnormal. Scripps Clinic physicians reviewed the records and concluded that the intention had been to code the testes normal. These results were recoded to reflect that finding. All changes were noted on the data collection forms.

All laboratory outliers were reviewed and adjudicated by an auditing physician. Each outlier was adjudicated using the following four codes:

1. Clinically explained or plausible (participant has single outlier)
2. Clinically explained or plausible (participant has multiple outliers)
3. Abnormal outlier not clinically explained but plausible
4. Abnormal outlier not clinically explained and not plausible.

These clinical judgments were included in the processing files. In the 1997 follow-up study, no laboratory outliers were coded as "4."

6.5 MEDICAL RECORDS CODING QC

SAIC forwarded completed physical examination records and questionnaire data to the Air Force at Brooks Air Force Base, Texas, for diagnostic coding and verification of all subjectively reported conditions. The Air Force used the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) for morbidity coding; the Systematized Nomenclature of Medicine for anatomic site coding; and the American Hospital Formulary Service for medication coding. Two medical records technicians independently processed each questionnaire and physical examination. Both codings were then subjected to a 100-percent QA review, during which every posted code was checked against medical records. A third medical records technician adjudicated any discrepancies.

6.6 STATISTICAL ANALYSIS QC

Specific QC measures were developed for the statistical analysis efforts. The tasks requiring QC included construction of databases for the analysis of each clinical chapter, the statistical analysis itself, and the preparation of the clinical chapters.

Each specialized statistical database was constructed by defining and locating every variable within the many subparts of the composite follow-up database. Although the data had been subjected to QA procedures during collection, statistical checks for outliers and other improbable values were conducted. Anomalies identified by the statisticians were discussed with those responsible for the data collection (i.e., NORC, Scripps Clinic, or the Air Force).

QA largely depended on regular communication and general agreement among statisticians. Several meetings and consultations between the Air Force team and SAIC statisticians were held in conjunction with the development of the data analysis plan. In addition, many telephone conversations took place during the course of the physical examination. During the analysis, there were frequent telephone conversations, and any problems identified in the statistical analysis were resolved by team discussion. Specialized SAS® programs were developed by the task manager for each type of analysis (exposure, longitudinal, dependent variable-covariate associations) and form of the dependent variable (continuous, dichotomous, polytomous). The software was checked by comparing results from analyses on the same variable by different programs. These programs were adapted for use in all clinical areas by changing the data source, dependent variable, covariates, and exclusions, so that a consistent statistical methodology could be applied to all clinical areas. Modifications to the programs were made only as necessary (e.g., a sparse number of abnormalities that necessitated the exclusion of a particular covariate). Each analysis and the summary statistics reported for the analysis were replicated independently by a separate statistician. The analyses were conducted in accordance with the data analysis plan, which was reviewed

extensively by SAIC and the Air Force. Throughout the study, the Air Force and SAIC maintained duplicate databases. Upon completion of the analyses, SAIC delivered all analysis software and SAS® data sets for each clinical area to the Air Force for final review and archiving.

All tables and statistical results were checked against the computer output from which they were derived, and all statistical statements in the texts were checked for consistency with the results given in the tables. In addition, drafts of each chapter in this report were reviewed by the Air Force and SAIC investigators.

6.7 ADMINISTRATIVE QA

In recognition of the magnitude, complexity, and importance of the AFHS, SAIC created an internal Quality Review Committee (QRC). The QRC was established at the initiation of the 1985 follow-up and continued through the 1987, 1992, and 1997 follow-up studies. Its purpose was to provide general oversight to the AFHS program and advice on the appropriateness of program management and QC actions. The QRC comprised SAIC senior corporate personnel and consultants. These independent reviewers remained separate from the project management staff. The QRC met periodically to review study progress and any issues that either had an impact on study quality or were perceived as a potential problem. Members of the QRC also conducted first-hand evaluations of ongoing program operations.

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